

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

THIS DOCUMENTS RELATES TO:
*State of Nevada v. American Home Products
Corp., et al.,*
No. CV-N-02-0020-ECR

MDL 1456

Master File No. 01-CV-12257-PBS

Judge Patti B. Saris

**IMMUNEX CORPORATION'S ANSWER TO
STATE OF NEVADA'S AMENDED COMPLAINT**

Defendant Immunex Corporation ("Immunex") answers the Amended Complaint ("AC"), dated as of August 1, 2003, as follows:

The AC improperly and repetitively refers to Immunex and other defendants and third parties on a collective basis, failing to plead with requisite particularity allegations against Immunex.

Immunex was acquired by defendant Amgen during this litigation but remains separately incorporated. Immunex is not responsible for the actions of Amgen, and Amgen is not responsible for the actions of Immunex. Amgen has assumed the marketing of Enbrel, and it will answer as to Enbrel and all related activities.

Intentionally ambiguous pleading is improper and insufficient to apprise Immunex in any meaningful sense of the allegations asserted against it. Immunex has nevertheless

attempted to respond to the State's allegations to the extent possible under the circumstances. To the extent allegations refer to the knowledge, conduct, or actions of other defendants or entities, Immunex is without knowledge or information sufficient to form a belief as to the truth of those allegations and, on that basis, Immunex denies those allegations. Immunex answers the State's allegations on behalf of itself only, even when the State's allegations refer to alleged conduct by Immunex and other persons or entities. The AC improperly mixes factual allegations with inflammatory rhetoric so as to make it virtually impossible to respond meaningfully. Many of the allegations of the AC are vague or conclusory. The AC also includes terms that are undefined and susceptible to different meanings. By addressing factual allegations and not pointing out each and every ambiguity or challenging every innuendo or conclusion, Immunex does not admit any of the State's interpretations or conclusions. To save space, Immunex will not repeat the above and similar caveats each time they apply.

The AC contains purported quotations from a number of sources, many of which are unidentified. Referencing or purporting to summarize a potential item of evidence is not an allegation and does not require an answer. In responding to allegations consisting of quotations, an admission that the material quoted was contained in a document or was uttered by the person or entity quoted shall not constitute an admission that the substantive content of the quote was or was not true at the time the document was created, much less before or after its creation, or that the material is relevant or admissible in this action.

Immunex denies each and every allegation contained in the AC, except as specifically admitted, and any factual allegation admitted is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, innuendo, or speculation contained in or suggested by any allegation or the AC as a whole. Moreover, Immunex

specifically denies any allegations contained in headings, footnotes, the Table of Contents, and unnumbered paragraphs in the AC.

References to "the State" and similar references include not only the State of Nevada but each person or entity on whose behalf plaintiff seeks, directly or indirectly, to pursue this action.

These comments and objections are incorporated, to the extent appropriate, into each numbered paragraph of this Answer. Immunex numbers its answering paragraphs below to reflect the relevant paragraph or paragraphs in the AC.

1. Immunex admits that the State purports to bring this alleged action against Immunex and other pharmaceutical companies but otherwise denies each other or different allegation of Paragraph 1. Immunex denies that the State is entitled to maintain this action in the manner alleged. Immunex further denies the existence of, and its participation in, any "AWP scheme."

2. Immunex admits that it has manufactured or distributed certain medicines in Nevada as alleged in Paragraph 2. Immunex admits that payors for prescription pharmaceuticals include federal and/or state governments, private insurers and self-insured employers, and private individuals. Except as specifically admitted and to the extent that any remaining allegations are directed at Immunex and require a response, Immunex denies those allegations.

3. Paragraph 3 contains no allegations against Immunex and therefore requires no answer from Immunex.

4. Immunex admits that it spent money to develop and market drugs. Immunex denies the existence of, or its participation in, any "profit incentive" scheme as alleged in Paragraph 4. Except as specifically admitted and to the extent that any remaining

allegations are directed at Immunex and require a response, Immunex denies those allegations.

5 – 6. Immunex admits that certain medicines are covered under Medicare Part B, and that during certain times Congress mandated that Medicare Part B reimbursement be based upon AWP, an industry practice and term of art incorporated by the government as a reimbursement benchmark, and that Medicare Part B medicines are generally administered in a healthcare provider's office. Immunex admits that it reports some pricing information for its medicines to independent pharmaceutical industry publications. Immunex admits that AWP benchmarks published in trade publications can be higher than the prices ultimately paid by providers. Immunex denies the existence of, and its participation in, any "AWP scheme" or "unlawful agreement" as alleged in Paragraph 6. Except as specifically admitted and to the extent that any remaining allegations are directed at Immunex, Immunex denies those allegations in Paragraphs 5 – 6.

7. Immunex denies the existence of, and its participation in, any "AWP scheme" or "AWP Inflation Scheme" as alleged in Paragraph 7. Immunex denies that it "fraudulently reports" its drugs on a "fictitious and fraudulent AWP." To the extent that the remaining allegations in Paragraph 7 are directed at Immunex, Immunex denies those allegations.

8. Immunex admits that certain medicines are covered under Medicare Part B, and that during certain times Congress mandated that Medicare Part B reimbursement be based upon AWP, an industry practice and term of art incorporated by the government as a reimbursement benchmark, and that Medicare Part B medicines are generally administered in a healthcare provider's office. Immunex admits that AWP benchmarks published in trade publications can be higher than the prices ultimately paid by providers. Immunex denies that it has engaged "secret profits" or "inflated AWP schemes" as alleged in Paragraph 8.

Except as specifically admitted and to the extent that any remaining allegations are directed at Immunex, Immunex denies those allegations.

9. To the extent the allegations in Paragraph 9 are directed at and require a response from Immunex, Immunex denies those allegations.

10. Immunex denies the existence of, and its participation in, any "perversion of the type of competitive behavior" as alleged in Paragraph 10, and denies any remaining allegation.

11 – 12. Because the Court dismissed the Best Price claims in its Order dated June 10, 2004, a response is not required for Paragraph 11 – 12. To the extent a response is required, Immunex denies the allegations in Paragraphs 11 – 12.

13. Immunex denies the allegations in Paragraph 13.

14-17. Immunex denies the existence of, and its participation in, any "AWP Inflation Scheme" or "illegal AWP Scheme" as alleged in Paragraphs 15 – 17. Because the Court dismissed the Best Price claims in its Order dated June 10, 2004, a response is not required for certain allegations in Paragraph 15. Except as specifically admitted and to the extent that any remaining allegations in Paragraphs 14 – 17 are directed at and require a response from Immunex, Immunex denies those allegations.

18. Immunex admits that the State purports to bring this action as alleged in Paragraph 18, but Immunex denies that the State is entitled to maintain this action in the manner alleged. Except as specifically admitted and to the extent that the remaining allegations in Paragraph 18 are directed at Immunex, Immunex denies those allegations.

19 – 20. Immunex denies the existence of, and its participation in, any "AWP Inflation Scheme" as alleged in Paragraphs 19 – 20 and denies any remaining allegations.

21 – 23. Immunex admits that the State purports to bring this action as alleged in Paragraphs 21 – 23, but Immunex denies that the State is entitled to maintain this action in the manner alleged. Except as specifically admitted and to the extent that the remaining allegations in Paragraphs 21 – 23 are directed at Immunex, Immunex denies those allegations.

24. Immunex admits that the State purports to bring this action, and that the State seeks relief as alleged in Paragraph 24. Immunex denies that this action can be maintained in the manner alleged, and further denies that the State is entitled to relief under Counts I through VI. Except as specifically admitted and to the extent that the remaining allegations in Paragraph 24 are directed at Immunex and require a response, Immunex denies those allegations.

25. Immunex denies the allegations in Paragraph 25.

26. Immunex admits that its products have been sold in the State of Nevada. Except as specifically admitted and to the extent that the remaining allegations in Paragraph 26 are directed at Immunex and require a response, Immunex denies those allegations.

27 – 51. The allegations in Paragraphs 27 – 51 are directed to other defendants and contain no allegations against Immunex and therefore require no answer from Immunex.

52. Immunex admits that it became a wholly-owned subsidiary of Amgen, Inc., during the pendency of this litigation and that its principal place of business as of the commencement of the action is Seattle, Washington. Immunex admits that it developed products for the treatment of cancer, asthma, rheumatoid arthritis, inflammatory diseases, infectious diseases, and cardiovascular diseases. Immunex's Annual Reports speak for themselves. Except as specifically admitted, Immunex denies any and all remaining allegations in Paragraph 52.

53. Immunex admits that it was acquired by Amgen in July 2002. Immunex denies any and all remaining allegations in Paragraph 53.

54. Immunex admits that it manufactured and distributed several pharmaceuticals that were administered by Medicare Plan B providers in most if not all states. Immunex denies any and all remaining allegations in Paragraph 54.

55 – 76. The allegations in Paragraphs 55 – 76 are directed to other defendants and contain no allegations against Immunex and therefore require no answer from Immunex.

77. Paragraph 77 contains no allegations against Immunex and therefore requires no answer from Immunex.

78 – 86. Immunex states that the Chartbook, Chartbook Update, and Fact Sheet cited in Paragraphs 78 – 86 are the best evidence of their contents, but does not admit that the contents were accurate when created. Immunex denies that the State has accurately characterized the Chartbook, Chartbook Update, or Fact Sheet or that such are applicable to Immunex. Immunex further alleges that it is without information sufficient to form a belief concerning the accuracy of the allegations of Paragraph 78 – 86 and therefore denies those allegations.

87. Immunex is without information sufficient to form a belief concerning the accuracy of the allegations of Paragraph 87 and therefore denies those allegations.

88. Immunex denies the allegations of Paragraph 88.

89. Paragraph 89 contains no allegations against Immunex and therefore require no answer from Immunex. To the extent a response is required, Immunex denies the allegations in Paragraph 89.

90 – 93. Paragraphs 90 – 93 contain no allegations against Immunex and therefore require no answer from Immunex.

94. Immunex admits that it distributed pharmaceuticals through wholesalers, retailers, hospitals, providers, and managed care organizations. Except as specifically admitted and to the extent that the remaining allegations in Paragraph 94 are directed at Immunex and require a response, Immunex denies those allegations.

95. Immunex states that the Chartbook cited in Paragraph 95 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that the State has accurately characterized the Chartbook or that such is applicable to Immunex. Immunex further alleges that it is without information sufficient to form a belief concerning the accuracy of the remaining allegations of Paragraph 95 and therefore denies those allegations.

96 & 99. Immunex admits that "WAC" is an acronym for "wholesale acquisition cost" and that "DP" is an acronym for "direct price." Except as specifically admitted and to the extent that the remaining allegations in Paragraphs 96 and 99 are directed at Immunex and require a response, Immunex denies those allegations.

97. Immunex admits that the Medicare Part B program used AWP as a reimbursement benchmark. Except as specifically admitted and to the extent that the remaining allegations in Paragraph 97 are directed at Immunex and require a response, Immunex denies those allegations.

98 & 104. Immunex states that the Chartbook cited in Paragraphs 98 and 104 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that the State has accurately characterized the Chartbook or that such is applicable to Immunex. Immunex further alleges that it is without information sufficient to form a belief concerning the accuracy of the remaining allegations of Paragraphs 98 and 104 and therefore denies those allegations.

100. Immunex is without information sufficient to form a belief concerning the accuracy of the allegations in Paragraph 100 and therefore denies those allegations.

101 – 103. Paragraphs 101 – 103 contain no allegations against Immunex and therefore require no answer from Immunex. To the extent that Paragraphs 101 – 103 require a response from Immunex, Immunex alleges that it is without information sufficient to form a belief concerning the accuracy of the remaining allegations of Paragraphs 101 – 103 and therefore denies those allegations.

105. Immunex admits that DP generally is the price referenced when there are no applicable discounts. Except as specifically admitted and to the extent that the remaining allegations in Paragraph 105 are directed at Immunex and require a response, Immunex denies those allegations.

106. Immunex admits that the Medicare Part B program used AWP as a reimbursement benchmark. Except as specifically admitted and to the extent that the remaining allegations in Paragraph 106 are directed at Immunex and require a response, Immunex denies those allegations.

107 – 108. Immunex admits the allegations in Paragraphs 107 – 108.

109 – 110. Paragraphs 109 – 110 contain no allegations against Immunex and therefore require no answer from Immunex.

111. Immunex admits that 42 C.F.R. § 405.517 set forth the reimbursement methodology for drugs covered by Medicare Part B and is the best evidence of its contents. Immunex is without information sufficient to form a belief concerning the accuracy of the remaining allegations of Paragraph 111 and therefore denies those allegations.

112 – 113. Immunex admits that the Medicare Part B program used AWP as a reimbursement benchmark. Immunex denies the allegations in the first sentence of

Paragraph 112 insofar as it contains material in quotation marks the source of which is not identified. Immunex admits that 42 C.F.R. § 405.517 was amended on January 1, 1998, to "provide that the allowed amount would be based upon the lower of the billed charge on the Medicare claim form or 95 percent of AWP." Immunex denies any and all remaining allegations in Paragraphs 112 – 113 that pertain to it.

114 – 115. Immunex admits that the Medicare Program had publicly announced its use of the AWP as a reimbursement benchmark. Immunex states that Program Memo AB-99-63 cited in Paragraphs 114 – 115 is the best evidence of its contents. Immunex denies any and all remaining allegations in Paragraphs 114 – 115 that pertain to it.

116. Immunex admits that there are no regulations that describe how AWPs are to be calculated or a regulatory process specifically designated for approving AWPs. Immunex admits that there are several independently produced pharmaceutical industry compendia that periodically publish AWP and other reimbursement benchmarks and prices. Immunex also admits that it reports certain pricing information for its medicines to independent pharmaceutical industry publications. Except as specifically admitted, Immunex denies any and all remaining allegations in Paragraph 116 that pertain to it.

117 – 118. Paragraphs 117 – 118 contain no allegations against Immunex and therefore require no answer from Immunex.

119 - 122. Immunex states that the Reports cited in Paragraphs 119 – 122 are the best evidence of their contents, but does not admit that the contents were accurate when created. Immunex denies that the State has accurately characterized the reports or that such are applicable to Immunex. Immunex further alleges that it is without information sufficient to form a belief concerning the accuracy of the remaining allegations in Paragraphs 119 – 122 and therefore denies those allegations.

123. Paragraph 123 contains no allegations against Immunex and therefore requires no answer from Immunex.

124. Immunex admits that 42 C.F.R. § 440.120 defines prescription drugs and is the best evidence of its content. Except as specifically admitted, Immunex denies any and all remaining allegations in Paragraph 124 that pertain to it.

125. Immunex alleges that it is without information sufficient to form a belief concerning the accuracy of the remaining allegations in Paragraph 125 and therefore denies those allegations.

126. Immunex admits that the Nevada Medicaid Services Manual cited in Paragraph 126 is the best evidence of its content, but does not admit that the contents were accurate when created. Immunex denies that the State has accurately characterized the manual. Except as specifically admitted, Immunex denies any and all remaining allegations in Paragraph 126 that pertain to it.

127. Paragraph 127 contains no allegations against Immunex and therefore require no answer from Immunex.

128. Immunex is without information sufficient to form a belief concerning the accuracy of the allegations in Paragraph 128 and therefore denies those allegations.

129. Immunex admits that the Medicare Part B program used AWP as a reimbursement benchmark. Immunex denies any and all remaining allegations in Paragraph 129 that pertain to it.

130. Immunex admits that there are several independently produced pharmaceutical industry compendia that periodically publish AWP and other reimbursement benchmarks and prices. Immunex denies any and all remaining allegations in Paragraph 130 that pertain to it.

131. Immunex admits that it reported certain pricing information for its medicines to independent pharmaceutical industry publications. Immunex denies any and all remaining allegations in Paragraph 131 that pertain to it.

132. Immunex denies the allegations in Paragraph 132.

133 – 134. The April 2003 OIG report cited in Paragraphs 133 – 134 is the best evidence of its contents, but Immunex does not admit that the contents were accurate when created. Immunex denies that the State has accurately characterized any alleged OIG finding, opinion, statement or conclusion, or that such are applicable to Immunex or are retroactive. Immunex denies any and all remaining allegations in Paragraphs 133 – 134 that pertain to it.

135. Immunex denies the allegations in Paragraph 135.

136 – 138. Immunex denies the existence of, and its participation in, any "AWP Inflation Scheme" as alleged in Paragraphs 136 – 138. To the extent that the remaining allegations in Paragraphs 136 – 138 are directed at Immunex and require a response, Immunex denies those allegations.

139. Immunex admits that it reported certain pricing information for its medicines to independent pharmaceutical industry publications. Immunex denies any and all remaining allegations in Paragraph 139 that pertain to it.

140. Immunex denies the allegations in Paragraph 140.

141 & 143. Immunex denies the existence of, and its participation in, any "scheme" as alleged in Paragraphs 141 and 143. To the extent that the remaining allegations in Paragraphs 141 and 143 are directed at Immunex and require a response, Immunex denies those allegations.

142. Immunex admits that it reported certain pricing information for its medicines to independent pharmaceutical industry publications. Immunex also admits that the Medicare Part B program used AWP as a reimbursement benchmark. Immunex denies any and all remaining allegations in Paragraph 142 that pertain to it.

144 – 147. Immunex denies the allegations in Paragraphs 144 – 147.

148. Immunex denies the existence of, and its participation in, any "scheme" as alleged in Paragraph 148. To the extent that the remaining allegations in Paragraph 148 are directed at Immunex and require a response, Immunex denies those allegations.

149 – 150. Immunex admits that the Medicare Part B program used AWP as a reimbursement benchmark. Immunex also admits that 42 C.F.R. § 405.517 is the best evidence of its content. Except as specifically admitted, Immunex denies any and all remaining allegations in Paragraphs 149 – 150 that pertain to it.

151 – 152. Immunex admits that the Medicare Part B program used AWP as a reimbursement benchmark. Immunex also admits that 42 C.F.R. § 447.332(b) and the Nevada Medicaid program are the best evidence of their contents. Except as specifically admitted, Immunex denies any and all remaining allegations in Paragraphs 151 - 152 that pertain to it.

153 – 154. Immunex denies the allegations of Paragraphs 153 – 154.

155. Immunex admits that the State purports to quote from an unidentified "industry consultant" as alleged in Paragraph 155, but Immunex denies any allegations suggested by the quoted material.

156. Immunex admits that the Medicare Part B program used AWP as a reimbursement benchmark. Except as specifically admitted and to the extent that any

remaining allegations are directed at Immunex and require a response, Immunex denies those allegations.

157. Paragraph 157 contains no allegations against Immunex and therefore requires no answer from Immunex. To the extent a response is required, Immunex denies the allegations in Paragraph 157.

158. Immunex denies the allegations in Paragraph 158.

159 – 163. Immunex states that the *Red Book* and the unidentified DOJ report cited in Paragraph 159 and the pleadings cited in Paragraphs 160 – 163, are the best evidence of their contents, but does not admit that the contents were accurate when created. To the extent the allegations in Paragraphs 159 – 163 are deemed to include allegations against Immunex, Immunex denies such allegations.

164 – 172. Immunex denies the allegations in Paragraphs 164 – 172 that pertain to it.

173. Immunex admits that some governmental agencies have conducted investigations concerning pricing in the pharmaceutical industry. Immunex denies the remaining allegations in Paragraph 173 that pertain to it.

174 – 175. Immunex denies the existence of, and its participation in, any "scheme" cited in Paragraph 174. Immunex states that the September 28, 2000, letter from Congressman Stark to the President of Pharmaceutical Research and Manufacturers of America cited in Paragraphs 174 – 175 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that the State has accurately characterized the findings, opinions, statements, or conclusions of Congressman Stark, or that such are applicable to Immunex.

176. Immunex admits that some governmental agencies have conducted investigations concerning pricing in the pharmaceutical industry. Immunex denies any and all remaining allegations in Paragraph 176 that pertain to it.

177 – 178. Immunex denies any allegations in Paragraphs 177 – 178 that pertain to it.

179 - 285 The allegations in Paragraphs 179 – 285 are directed to other defendants and require no response from Immunex. To the extent allegations in Paragraphs 179 – 285 are deemed to include allegations against Immunex, Immunex denies them.

286 – 287. Immunex denies the existence of, and its participation in any "scheme" as alleged in Paragraphs 286 – 287. Immunex denies that it has stated "fraudulent AWPs." Immunex denies that the State is entitled to judgment or any relief and denies any other allegations in Paragraphs 286 – 287 that pertain to it.

288. Immunex admits that it reported certain pricing and reimbursement information for its medicines to independent pharmaceutical industry publications during the purported time period. Immunex admits that on occasion prior to July 1995 it reported suggested AWPs to independent pharmaceutical industry publications. Immunex states that the October 26, 2000, letter is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that the State has accurately characterized the letter. Immunex states that the interview cited in document IAWP003071 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that the conclusions the State has drawn from the documents cited in Paragraph 288 are accurate and denies any and all remaining allegations in Paragraph 288.

289. Immunex states that the January 12, 1996, letter is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex states that the January 12, 1995, letter is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex admits that it reported certain pricing and reimbursement information for its medicines to independent pharmaceutical industry publications during the purported time period. Immunex admits that on occasion prior to July 1995 it reported suggested AWPs to independent pharmaceutical industry publications. Immunex denies any conclusions the State has drawn from the documents cited in Paragraph 289 and denies any and all remaining allegations in Paragraph 289.

290. Immunex denies the existence of, and its participation in any "scheme" as alleged in Paragraph 290. Immunex denies any and all remaining allegations in Paragraph 290.

291. Immunex states the "internal document" cited in Paragraph 291 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that the conclusions the State has drawn from the document cited in Paragraph 291 are accurate and denies any and all remaining allegations in Paragraph 291.

292 – 293. Immunex admits that it understood that AWP was a reimbursement benchmark. Immunex states that "internal documents" IAWP012961 and IAWP051149-52 are the best evidence of their contents, but does not admit that the contents were accurate when created. Immunex denies any conclusions the State has drawn from the documents cited in Paragraphs 292 – 293 and denies any and all remaining allegations in Paragraphs 292 – 293.

294. Immunex states that the February 21, 1997, memo is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies

any conclusions the State has drawn from the documents cited in Paragraph 294 and denies any and all remaining allegations in Paragraph 294.

295. Immunex states that documents IAWP003407-13 and IAWP016686-88 are the best evidence of their contents, but does not admit that the contents were accurate when created. Immunex denies any conclusions the State has drawn from the documents cited in Paragraph 295 and denies any and all remaining allegations in Paragraph 295.

296. Immunex admits that it produced documents pursuant to government requests. Immunex admits that the State has reviewed such documents and that each such document is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that the State has accurately characterized such documents or that such conclusions the State has drawn are accurate and denies any and all remaining allegations in Paragraph 296.

297. Immunex states that document IAWP005418 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies any conclusions the State has drawn from the document. Immunex denies all remaining allegations in Paragraph 297.

298. Immunex denies the existence of, and its participation in any "scheme" as alleged in Paragraph 298. Immunex admits that the governmental agencies listed in Paragraph 298 have conducted investigations concerning pricing in the pharmaceutical industry and that Immunex has received and responded to requests for information. Immunex denies any and all remaining allegations in Paragraph 298.

299. Immunex admits that it distributed methotrexate sodium and leucovorin calcium in 1997 and that the AWP reimbursement benchmark for the drugs might have been higher than the actual prices paid by some customers of wholesalers. Immunex states that

the DHHS Report cited in Paragraph 299 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that the State has accurately characterized the DHHS Report and denies any and all remaining allegations in Paragraph 299.

300. Immunex admits that it distributed Novantrone® in 1997 and that the AWP reimbursement benchmark for the drug was higher than the actual prices that might have been paid by some customers of wholesalers. Immunex states that the DHHS 1997 Report is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that the State has accurately characterized the DHHS 1997 Report and denies any and all remaining allegations in Paragraph 300.

301. Immunex states that document IAWP016524 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies any conclusions the State has drawn from the document cited in Paragraph 301 and denies any and all remaining allegations in Paragraph 301.

302 – 382. The allegations in Paragraphs 302 – 382 are directed to other defendants and require no response from Immunex. To the extent allegations in Paragraphs 302 – 382 are deemed to include allegations against Immunex, Immunex denies them.

383 – 403. Because the Court dismissed the Best Price claims in its Order dated June 10, 2004, Immunex does not respond to the Best Price allegations contained in Paragraphs 383 – 403. To the extent a response is required and the allegations in Paragraphs 383 – 403 are deemed to include allegations against Immunex, Immunex denies them.

404. Immunex denies the allegations in Paragraph 404.

405. Immunex states that the 2003 CMS document cited in Paragraph 405 is the best evidence of its contents, but does not admit that the contents were accurate when

created. Immunex denies that the State has accurately characterized any alleged CMS finding, opinion, statement, or conclusion. Immunex admits that it sells its medicines in competitive markets and, as such, takes steps to keep certain information relating to its medicines confidential. Immunex denies any and all remaining allegations in Paragraph 405 that pertain to it.

406 – 409. Immunex denies any allegations in Paragraphs 406 – 409 that pertain to it.

410. In response to the allegations in Paragraph 410, Immunex denies that the State lacked inquiry or other notice of the issues associated with reliance on AWPs as a reimbursement benchmark. Immunex specifically alleges, to the contrary, that such issues were well-known for more than a decade before the State elected to bring this suit and that the State's allegations in the suit estop it from denying that it was on inquiry or other notice.

411 – 412. The allegations in Paragraphs 411 – 412 state legal conclusions to which no response is required. Immunex denies any allegations in Paragraphs 411 – 412 that pertain to it.

413. Immunex denies the existence of, and its participation in any "scheme" as alleged in Paragraph 413. Immunex denies any and all remaining allegations in Paragraph 413.

414. Paragraph 414 contains no allegations against Immunex and therefore requires no answer from Immunex.

415 – 417. Immunex is without information sufficient to form a belief concerning the accuracy of the allegations in Paragraphs 415 – 417 and therefore denies those allegations.

418. Immunex admits that some Medicare beneficiaries obtain supplemental insurance. Except as specifically admitted, Immunex denies any and all remaining allegations in Paragraph 418.

419 – 422. Immunex denies the existence of, and its participation in any "scheme" as alleged in Paragraphs 419 – 422. Immunex denies any and all remaining allegations in Paragraphs 419 – 422.

423. Immunex realleges and incorporates its responses to the allegations in Paragraphs 1 – 422 in answering Paragraph 423.

424. Immunex denies the existence of, and its participation in any "scheme" as alleged in Paragraph 424. Immunex denies any and all remaining allegations in Paragraph 424.

425 – 429. Immunex denies the allegations in Paragraphs 425 – 429 that pertain to it. Immunex further denies that the State has suffered damages or injuries as alleged in Paragraphs 425 – 429.

Immunex denies the State is entitled to a judgment or any other relief requested in the Prayer for Relief for Count I.

430. Immunex realleges and incorporates its responses to the allegations in Paragraphs 1 – 429 in answering Paragraph 430.

431 – 436. Immunex denies the existence of, and its participation in, any "AWP Scheme" as alleged in Paragraph 433. Immunex denies any remaining allegations in Paragraphs 431 – 436 and subparts that pertain to it. Immunex further denies that the State has suffered damages or injuries as alleged in Paragraphs 431 – 436.

Immunex denies the State is entitled to a judgment or any other relief requested in the Prayer for Relief for Count II.

437. Immunex realleges and incorporates its responses to the allegations in Paragraphs 1 – 436 in answering Paragraph 437.

438 – 443. Immunex denies the existence of, and its participation in, any "AWP Scheme" as alleged in Paragraph 438. Because the Court dismissed the Best Price claims in its Order dated June 10, 2004, Immunex does not respond to the Best Price allegations contained in Paragraph 438. Immunex denies any remaining allegations in Paragraphs 438 – 443 and subparts that pertain to it. Immunex further denies that the State has suffered damages or injuries as alleged in Paragraphs 438 – 443.

Immunex denies the State is entitled to a judgment or any other relief requested in the Prayer for Relief for Count III.

444. Immunex realleges and incorporates its responses to the allegations in Paragraphs 1 – 443 in answering Paragraph 444.

445 – 466. Because the Court dismissed Nevada's racketeering claims in its Order dated June 10, 2004, a response is not required for Paragraphs 445 – 466.

Immunex denies the State is entitled to a judgment or any other relief requested in the Prayer for Relief for Count IV.

467. Immunex realleges and incorporates its responses to the allegations in Paragraphs 1 – 466 in answering Paragraph 467.

468. Immunex admits that the State purports to bring this action as alleged in Paragraph 468, but Immunex denies that this State is entitled to maintain this action in the manner alleged. Except as specifically admitted and to the extent that the remaining allegations in Paragraph 468 are directed at Immunex, Immunex denies those allegations.

469. Immunex admits that it was listed in the Nevada Medicaid drug formulary. Except as specifically admitted, Immunex denies any and all remaining allegations in Paragraph 469.

470 – 474. Because the Court dismissed the Best Price claims in its Order dated June 10, 2004, a response is not required for Paragraphs 470 – 474.

475 – 477. Because the Court dismissed the Best Price claims in its Order dated June 10, 2004, Immunex does not respond to the Best Price allegations contained in Paragraph 477. Immunex denies the allegations in Paragraphs 475 – 477 and subparts that pertain to it. Immunex further denies that the State has suffered damages or injuries as alleged in Paragraphs 475 – 477.

Immunex denies the State is entitled to a judgment or any other relief requested in the Prayer for Relief for Count V.

478. Immunex realleges and incorporates its responses to the allegations in Paragraphs 1 – 477 in answering Paragraph 478.

479. Immunex denies the allegations in Paragraph 479.

Immunex denies the State is entitled to a judgment or any other relief requested in the Prayer for Relief for Count VI.

DEFENSES

Without assuming any burden that it would not otherwise have, and without waiving any denial above, Immunex further responds to the AC by alleging the following:

1. The Complaint fails to state a claim upon which relief may be granted.
2. Immunex has not acted in a manner that is illegal, oppressive, or fraudulent and in fact acted in good faith, with just cause, and in accordance with established industry practices and government requirements and policies.

3. The federal government adopted AWP as a reimbursement benchmark with knowledge that it was not a calculation of actual average prices and with no express or implicit definition contrary to industry practice. For public policy and other reasons, the federal government retained AWP as a reimbursement benchmark in the face of years of criticism that it was not a calculation of actual average prices. To the extent that the State has adopted the federal government's AWP term, the State is bound by defenses applicable to the federal government. Among the defenses that arise from those and other relevant circumstances are the following:
 - A. The State's claims are barred, in whole or in part, by the political question, separation of powers, and filed rate doctrines. The relief sought by the State would interfere with legislative decisions and functions.
 - B. The State's claims are barred, in whole or in part, because Immunex has complied with all applicable statutes and regulations.
 - C. The State's claims are barred, in whole or in part, because they violate Immunex' rights under the Due Process and Ex Post Facto clauses of the United States Constitution, as well as the Nevada State Constitution, insofar, among other things, as the State seeks to impose liability under vague or nonexistent standards or retroactively for conduct that was not actionable at the time it occurred.
 - D. The State's claims are barred, in whole or in part, because Immunex did not make any false statements to the State or its citizens.

Immunex had no reasonable grounds to believe, and did not believe, that any statement was false or misleading or capable of being false or misleading.

- E. The communications and conduct of Immunex and others are protected by the First Amendment, Nevada State Constitution, and common law privileges, and it would violate those protections to construe the AWP practice and term of art as fraudulent.
- F. The State's claims are barred, in whole or in part, by the government contractor and similar defenses because the reimbursement system, including the use of AWP in excess of actual average prices, was designed and approved by the United States Government to serve its purposes.
- G. Immunex relied on the policies and practices of the federal and Nevada state governments, and the State is estopped or otherwise barred from seeking to impose liability for such reliance.
- H. The State's approach to AWP would discourage legitimate price competition and is inconsistent with and preempted by the Sherman Act.
- I. The claims are barred, in whole or in part, because, *inter alia*, in directly or indirectly adopting "AWP" outside of its government reimbursement and industry context the State or those on behalf of whom it is acting acted recklessly and assumed all risks that it or its representatives might not understand it properly, because it is bound

by the federal government's knowledge and purposes, and because it consented to and ratified use of AWP.

4. The State's state law claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, the Federal Medicaid Act, regulations promulgated under those acts, and by the dormant Commerce Clause of the United States Constitution.
5. The State's claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or expressive conduct by Immunex, healthcare providers, or others directed at judicial, legislative, or administrative bodies of government.
6. The State's claims are barred, in whole or in part, by the applicable statutes of limitations and repose.
7. The State's claims are barred, in whole or in part, by the doctrines of laches, estoppel, and waiver.
8. The State has no standing or capacity to bring, and is not the real party in interest with respect to, some or all of the claims raised in this suit, including but not limited, to the State's asserted status in *parens patriae* to recover Medicaid or Medicare expenditures or to seek injunctive relief.
9. Immunex denies that the State has met the statutory and case law requirements under the Nevada Deceptive Trade Practices Act. However, if such claims are found to exist, Immunex pleads all available defenses under the Act, including standing, federal preemption, and lack of involvement.

10. The State's claims for declaratory or equitable relief are barred because the State has an adequate remedy at law, because the claims were rendered moot by the passage of the 2003 Medicare reform legislation, and due to the doctrine of *in pari delicto* or unclean hands.
11. The State's claims are barred, in whole or part, with respect to any alleged overcharge or supracompetitive price because third party payors passed on any effect of the alleged supracompetitive prices to their customers or employees in the form of higher premiums or in other ways; because such supracompetitive price, if any, was absorbed, in whole or part, by a person or entity that purchased the medicine directly, or by an intermediate indirect purchaser, and was not passed through; or because purchasers who paid directly or indirectly on the basis of an allegedly excessive AWP would have paid more with respect to this or other elements of health care pricing in the absence of AWP.
12. To the extent the State obtains or has obtained recovery or has benefited from another entity's recovery in this or any other case or through any other method predicated on the same factual allegations, the State is barred from seeking recovery against Immunex based on the AC.
13. The State's claims are barred, in whole or in part, to the extent it has released, settled, entered into an accord and satisfaction, or otherwise compromised its claims.
14. The State's claims are barred, in whole or in part, due to its failure to join indispensable parties.

15. The State's claims are barred, in whole or in part, because any injuries sustained by the State were the result of intervening or superceding conduct of third parties or of the State or its agents or representatives.
16. The State's claims are barred, in whole or in part, because they are speculative and remote and because of the impossibility of ascertaining and allocating of those alleged damages.
17. The State's claims are barred, in whole or in part, because it failed to mitigate its damages, and its failure to mitigate damages should proportionately reduce the recovery and the allocation of any fault, if any exists, attributable to Immunex.
18. The State's claims are barred, in whole or in part, because it would be unjustly enriched if allowed to recover any portion of the damages alleged in the AC.
19. Immunex is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by the State or those on whose behalf it acts with respect to the same alleged injuries.
20. Any damages recovered by the State from Immunex must be limited by any applicable statutory ceilings on recoverable damages.
21. Any punitive damages would be excessive, penal in nature, and subject Immunex to multiple and retroactive liability and deny Immunex constitutionally adequate standards, instructions, and procedures.
22. The State's claims for punitive damages are barred by the Federal and Nevada State Constitution, common law, and public policies.

23. Maintenance of this action would violate the separation of powers provisions of the United States Constitution and would be an unconstitutional usurpation of authority reserved to the legislative branch.
24. Maintenance of this action in one proceeding against many defendants and absent those on whose behalf, directly or indirectly, the State pursues this action would violate Immunex' rights under the federal and state constitutions by denying Immunex procedural and substantive safeguards.
25. The State's claim for punitive and other damages against Immunex cannot be sustained because any award without the apportionment of the award separately and severally between or among the defendants and other alleged responsible parties, as determined by the alleged percentage of the wrong committed by each alleged tortfeasor, would violate Immunex' due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Nevada State Constitution, common law, and public policies.
26. Immunex maintained policies regarding samples, grants, and other issues that prohibited unlawful or questionable practices. Immunex regularly instructed relevant employees as to such policies. To the extent that Immunex had knowledge of conduct that could be viewed as improper, Immunex took prompt and reasonable steps to correct and halt such conduct, including disciplinary action against employees.
27. Immunex adopts by reference any additional applicable defense pled by any other defendant not otherwise pled in this answer. Immunex hereby gives notice that it intends to rely upon any other and additional defense that is now

or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserve its right to amend its answer to assert such defense. Immunex also reserves the right to assert such other and related defenses as may become available in the event of a determination that the action, or some part of it, is governed by the substantive law of the State of Nevada.

PRAYER FOR RELIEF

WHEREFORE, Defendant Immunex Corporation requests the following relief:

- A. Dismissal of the State's claims with prejudice;
- B. An award of attorneys' fees and costs; and
- C. Such other legal and equitable relief as the Court deems proper.

DATED this 12th day of July, 2004.

/s/ Gary M. Ronan
Thomas J. Sartory, BBO #442500
Gary M. Ronan, BBO #653899
GOULSTON & STORRS, P.C.
400 Atlantic Avenue
Boston, MA 02110-3333
(617) 482-1776
tsartory@goulstonstorrs.com
gronan@goulstonstorrs.com

David J. Burman, WSB #10611
Kathleen M. O'Sullivan, WSB #27850
Zoe Philippides, WSB #30532
Charles C. Sipos, WSB #32825
PERKINS COIE LLP
1201 Third Avenue, Suite 4800
Seattle, WA 98101-3099
(206) 359-8000
dburman@perkinscoie.com
kosullivan@perkinscoie.com
zphilippides@perkinscoie.com
csipos@perkinscoie.com

Attorneys for Defendant
IMMUNEX CORPORATION